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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,984	05/25/2006	Curtis Dobson	81599-002US0	5866

50670 7590 12/22/2009

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
12/22/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/580,984	DOBSON, CURTIS	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,11,13,14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) *10,11,13,14,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/14/08;4/15/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-8 and 18 in the response to restriction requirement and amendment filed October 9, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 10, 11, 13, 14 and 16-17 are directed to non-elected species and withdrawn from consideration. Therefore, claims 1-8 and 18 are examined.

Informalities

The disclosure is objected to because of the following informalities:

2. The specification recites the amino acid sequence of LRTRKRGRKLRTRKRGRK (GIN 16) as SEQ ID NO:2, at page 5, However, it also indicates RLTRKRGLKRLTRKRGLK is SEQ ID NO:2 at page 7 and in the Sequence Listing. Appropriate correction is required. Applicant must comply with the requirements of sequence rules (37 CFR 1.821-1.825) to include all the sequences in the Sequence Listing.

3. The specification recites amino acid sequences in Table 1 at page 8 without providing the sequence Identifier "SEQ ID NO:". If the amino acid sequence is part of the peptide sequence having "SEQ ID NO:Z", then the amino acid sequence can be indicated as residues x to y of SEQ ID NO:Z. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-7 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is directed to a polypeptide, derivative or analog thereof. As written, the claim does not explicitly indicate the hand of man. Insertion of "isolated or purified" in connection with the polypeptide is suggested. See MPEP § 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-8 and 18 are directed to a polypeptide, derivative or analogue thereof, comprising a tandem repeat of apolipoprotein B or a truncation thereof, characterized in that the tandem repeat or truncation thereof is derived from an HSPG receptor binding region of apolipoprotein B; and a composition comprising the polypeptide, derivative or analogue thereof.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other

materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification discloses that GIN16 (SEQ ID NO;2) has antiviral effect against HSV1 and some peptides comprising a tandem repeat from an HSPG receptor binding region of apolipoprotein B exhibit antiviral properties (pages 5-6, 11-12), the specification does not disclose a genus of variants for polypeptides, derivatives or analogues comprising a tandem repeat of apolipoprotein B or a truncation thereof, where the tandem repeat or truncation thereof is derived from an HSPG receptor binding of apolipoprotein B, and the functions of the peptide variants are not defined. The specification does not sufficiently describe the whole genus of peptide variants when there is substantial structural variation within the genus with no defined function. Several species of antiviral peptides (listed on pages 11-12) do not provide sufficient written description for the whole genus of peptide variants derived from an HSPG receptor binding of apolipoprotein B, but with no defined function. Without guidance on structure to function/activity of various peptides derived from an HSPG receptor binding of apolipoprotein

B, one skilled in the art would not readily identify a functional peptide. The lack of a structure to function/activity relationship for the peptides derived from an HSPG receptor binding of apolipoprotein B, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-8 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1-8 and 18 are indefinite because of the use of the term "derivative" or "derived from". The term cited renders the claim indefinite, it is not clear what structure the derivative has and how different the derivative is from its parent compound. The claims are also indefinite as to the term "HSPG", it is not clear what the term means. Claims 2-8 and 18 are included in the rejection because they dependent on a rejected claim and do not correct the deficiency of the claim from which they depend. Use the term "obtained from" or "from" instead of "derived from" is suggested. A fully spelled word should be indicated for the term "HSPG".

8. Claim 3 is indefinite because the claim recites a term "apoB3359-3367" without providing the reference sequence, it is not clear what sequence these residues refer to.

9. Claim 7 recites the amino acid sequence of LRTRKRGRKLRTRKRGRK (GIN 16) as SEQ ID NO:2, However, the Sequence Listing indicates RLTRKRGLKRLTRKRGLK is SEQ ID NO:2. Thus, it is not clear which sequence is SEQ ID NO:2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lunec *et al.* (WO 98/42751).

Lunec *et al.* teach a molecule having the sequence of RLTRKRGLKLA or a partially modified form thereof or analog thereof inhibits uptake by the high affinity LDL receptor of LDL, and the sequence is residues 3359-3369 of apoprotein B 100 (the paragraph bridging pages 2 and 3), where the sequence of RLTRKRGLKLA comprises the instant SEQ ID NO:1, RLTRKRGLK (claims 1-4). Lunec *et al.* also teach a composition comprising the molecule and a pharmaceutically acceptable carrier (page 4, the fourth paragraph; claim 8).

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
December 16, 2009